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510(k) Summary

Name of Sponsor:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(k) Contact Person:	**Dina L. Weissman, J.D.** Legal Consultant, Regulatory Affairs Phone: (574) 371-4905 FAX: (574) 371-4987
Trade Name:	**Biax A.F. Wrist/Biax Advanced Fixation Wrist**
Common Name:	Wrist prosthesis
Classification:	**Class II** Device per 21 CFR 888.3800: Wrist, 3-part metal-plastic articulation, semi-constrained cemented prosthesis
Device Product Code:	**87 JWJ**
Panel:	Orthopaedic
Performance Standards:	No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for a wrist prosthesis.
Substantially Equivalent Devices:	DePuy Biax Wrist **K842266** (Formerly called "Beckenbaugh Wrist Prosthesis") Kinetikos Universal Total Wrist System **K020554**
Device Description:	The Biax A.F. Wrist System is a cemented, multiple component system to be used for the treatment, and revision, of wrist joints: • The radial implant stem is made of ASTM F-75 Orthochrome with an articulating surface of UHWMPe. It is available in small, medium and large sizes. • The 5-piece metacarpal implant is manufactured from F-75 Orthochrome and Titanium (Ti-6Al-4V ELI). It consists of a fixation plate, cemented and held in place with a central stem and two peripheral screws, and attached to an articulating head. All parts are available in a variety of sizes.

510(k) Summary (continued)

Indications for use:

The DePuy Biax A.F. Wrist System is intended to give patients limited wrist mobility by reducing pain, restoring alignment and replacing both the flexion and extension movement in the wrist joint.

The Biax A.F. Wrist System is indicated for use as a replacement of wrist joints disabled by rheumatoid arthritis with pain, deformity and/or limited motion, degenerative or post-traumatic arthrosis, ankylosis of the wrist in malposition and advanced instability with carpal destruction.

The DePuy Biax A.F. Wrist System is also indicated for revision of a failed previous wrist surgery.

CAUTION: The DePuy Biax A.F. Wrist System is intended for cemented use only.

Substantial equivalence:

The Biax A.F. Wrist System has the same intended use, is manufactured from the same material, is sterilized and packaged in the same way, and has the same design features as the predicate devices and is therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2003

Ms. Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
Depuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K031203
Trade/Device Name: Biax A.F. Wrist System
Regulation Number: 21 CFR 888.3800
Regulation Name: Wrist joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWJ
Dated: April 14, 2003
Received: April 16, 2003

Dear Ms. Weissman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031203

Device Name: Biax A.F. Wrist

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Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K031203

Concurrence of CDRH, Office of Device Evaluation

Prescription Use Y (Per 21 CFR 801.109) OR Over-The-Counter Use N